Utah Department of Health

CLINICAL LABORATORY BULLETIN August 2008

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING

Sumaiya Islam	Chemistry
Soo Jin Kim	Molecular Biology

NOTEWORTHY

✓ **Working 4 Utah:** Beginning August 4, 2008 the Certification & Approval Section of the Bureau of Laboratory Improvement will join most state employees in changing to a 4 ten-hour workweek. Our section will be staffed Monday through Thursday from 6:30 AM to 5 PM. Email, voice mail and fax will remain available 24/7, but the building will be closed Fridays through Sunday. We will respond to your requests first thing Monday morning (unless it is one of those Monday holidays!).

✓ **Hemolysed specimens a problem?:** Daniel M. Baer, MD from the Oregon Health and Science University offered these suggestions in the May issue of MLO to reduce hemolysis in blood samples.

*Use an evacuated tube system – not a syringe – to collect samples.

*Use 21-guage needles

*Collect samples through an IV catheter no smaller than 20-guage.

*If you must use a syringe, do not use strong negative pressure to draw blood into it. When putting the blood into the evacuated tube, let the tube's vacuum draw the blood in – do not push on the syringe plunger.

*Use a trained phlebotomist who collects blood often.

✓ **Specific gravity and urine pregnancy tests:** In the previous century (like 1985) the specimen of choice for urine pregnancy was the "first morning specimen". That would help ensure a specific gravity of at least 1.015. This was a good sample for that generation of testing methods.

Now the colorimetric qualitative kits (report = positive or negative) are CLIA waived. The only requirement for a waived test is to follow the manufacturer's instructions. Unfortunately, the instructions regarding specific gravity may be hidden in the "limitation" section of the insert. It may say the accuracy would be affected by a sample with a specific gravity less than . . . In such a case, you would need to do a specific gravity to have confidence in the test result.

Karen M. Ringsrud, MT(ASCP) from the University of Minnesota Medical School responded to a question in the June 2008 issue of MLO about doing specific gravity testing before doing urine hCG tests. She stated a serum is preferred to a urine specimen. But consider, if you are using the same waived kit on the serum as you do on a urine, might the

CONTENTS

concentrated first morning specimen have more hormone to be detected? Also, any time you change to a different testing kit, read the entire package insert as methods vary. Specific gravity may be essential to the accuracy of one method and not another.

✓ **Bouncing PSA values:** Herbert A. Fritsche, PhD, chief of Clinical Chemistry at M.D. Anderson Cancer Center in Houston answered a question in the June issue of CAP today about variation in prostate-specific antigen (PSA) test values. The patient's initial result was 4.6 ng/mL. Two weeks after a biopsy, the test was repeated. The repeat sample results were 1.6 and 1.7 (repeat). Dr. Fritsche said the explanation for that type of variation is asymptomatic prostatitis. He said it may occur in as many as 10% of patients who do not have prostate cancer. His advice? Repeat the test at least once, preferably twice, a few weeks apart, before doing a biopsy.

✓ **Undiagnosed disease:** Do you have a friend, family member or patient who is chronically ill with multiple symptoms and no one seems able to diagnosis a medical condition? Maybe the clinician says "chronic fatigue syndrome" or worse, they think "hypochondriac". Now there is a group at the National Institutes of Health (NIH) working to diagnosis rare or unknown disease states.

The website has 6 categories: Rare Diseases Information, Patient Advocacy Groups, Research & Clinical Trials, Genetic & Rare Diseases Information Center, Co-funded Scientific Conferences and Genetics Information & Services. Check it out! (www.rarediseases.info.nih.gov/Undiagnosed) The center expected to be receiving patients July 2008.

✓ **FDA approved MRSA screen:** Thermo Fisher Scientific Inc. has FDA clearance for Remel to manufacturer and distribute their Spectra MRSA (methicillin resistant *Staphylococcus aureus*) screening test. The company states the culture plate provides high positive predictive results in 24 hours. (www.thermofisher.com)

✓ **Falsely elevated glucose readings:** An investigation was done when a diabetic patient went into hypoglycemic coma after being given too much insulin. The investigation found his whole blood glucose reading was artificially high due to maltose. The patient was given a 10% maltose-containing intravenous immune globulin solution. The maltose artificially raised the glucose reading on the Accu-Chek Inform meter. The test strip methodology was glucose dehydrogenase pyrroloquinoline-quinone.

Bottom line = **read those manufacturer's instructions (package inserts) for things that can interfere with that particular test method**. Not all waived blood glucose meters use the same method to test for glucose. What could affect one meter may not affect a different one.

✓ **Antibiotic resistance in Northern Utah UTI:** In the spring 2008 issue of Clinical Laboratory Science Michael McQuilkin, Alexander Lund, and Wyatt Palmer gave the results of an undergraduate study reported in 2007. The researchers tested 108 bacterial urine isolates from 120 healthy 18 to 50 year old women presenting with uncomplicated, community-acquired urinary tract infection (UTI). Susceptibilities were determined using the standard Kirby-Bauer disc diffusion method. The organisms were tested with SXT/TMP (21.3% resistance), ciprofloxacin (14.4% resistance) and nitrofurantoin (13.9% resistance).

The authors compared their findings with a 1997 to 2001 national trend study. All resistance rates were increased in Northern Utah in 2007 compared with the national

figures. Significant increases were seen for ciprofloxacin and nitrofurantoin. The authors conclude SXT/TMP is over the 20% resistance threshold to be used for empirical treatment. While the other two antibiotics are nearly equal, ciprofloxacin has been associated with tendinopathies. Therefore, the authors recommend nitrofurantoin as the drug of choice for treatment of female uncomplicated UTI in Northern Utah. They also recommend additional national resistance trend analysis.

✓ **Transfusions in Heart Surgery: the older the blood the poorer the outcome:** The Cleveland Clinic reported their study on heart surgery patients who received blood during or shortly after open heart surgery in the March 19, 2008 issue of *WebMD*. After controlling for a number of factors, the authors concluded death risk was 30% higher among patients transfused with blood stored longer than 14 days. Patients were more likely to have longer intubation, more kidney failure and infection. There was also a 2.6% increased death rate one year after surgery for patients given older blood.

✓ **Correct Rh immune globulin dosage:** The May 2008 issue of CAP Today contained an article entitled "Bringing new rigor to RhIG calculations". CAP's Transfusion Medicine Resource Committee developed a Rh immune globulin (RhIG) dose calculator. About 16% of women giving birth are Rh negative. Sixty per cent of their infants will be Rh positive and the mothers will need at least one 300 µg vial of RhIG. One vial counteracts about 30 mL fetal blood spilled into the mother's system. Determining when there is a significant bleed requiring more RhIG is the problem.

CAP's resource committee began by asking proficiency test participants to indicate how many RhIG vials they would give a particular patient based on the sample sent. Many said "none" when the correct answer should have been at least one. The authors claim the Kleihauer-Betke assay, developed in 1957 to determine when and how much RhIG to give, is tedious and error prone. They recommend using their calculator method and add one vial to the dosage for a safety margin.

"The illiterate of the 21st century will not be those who cannot read and write, but those who cannot learn, unlearn, and relearn."

Alvin Toffler

☆ Feature ☆

Pre-analytic Specimen Identification Errors

The results of a Q-Probes report entitled "Specimen Labeling Errors" appeared in the June 2008 issue of CAP Today. A 2007 Q-Probes reviewed 3.4 million specimens from 147 facilities. There were 3,043 labeling errors making the US laboratory error rate at least 13 per 10,000 labels (0.13 %).

The errors were divided into 5 categories – unlabeled specimens, mislabeled specimens, partially labeled specimens, incompletely labeled specimens and illegible labels. This study did **not** count specimens collected from the wrong patient. The report mentions two ways facilities were able to lower their label error rate. Those facilities with a current and ongoing quality monitoring system and those

with a dedicated, trained phlebotomy team available 24/7 had extremely low error rates.

Proper phlebotomy protocol should include at least 4 steps to prevent errors – including and especially drawing blood from the wrong patient (not captured in the above statistics).

. . Phlebotomist introduces herself / himself.

. . Double check the patient's identity. Check the wristband against the written order and check the written order against the labels and patient's wristband. For outpatients or alert hospitalized patients, ask them their name and birth date. One phlebotomist related the following incident to me just last week. She called for Alice Smith [names changed of course] from the waiting room. An elderly gentleman came into the draw station. She asked him if his name was Alice and he said, "Yes". Then she asked him to say his name, to which he replied, "Tom Carlisle".

. . Label the specimen before leaving the patient.

. . Check the labeled specimens against the patient's armband or paperwork. One large health care corporation in Utah requires able patients to check their labels on the tubes and sign that the information is correct.

Newer labeling technology using handheld Palm devices solves some technology problems such as mixing up labels printed at a remote site or faulty bar code readers.

The first step to lowering your facility's labeling error rate is to determine what it is right now. Track the errors on a simple sheet with slash marks for correctly labeled and maybe divide the problem side into the four categories listed above. Make the form very simple so it is easy to use. Then do simple training and continuous monitoring until the rate decreases (zero is probably a good number to aim for). Finally write a short article to your favorite journal to let others know how you succeeded!

Equals

"2000 mockingbirds: two kilomockingbirds (think about it!)"

CLIA BITS

ADDITIONAL WAIVED TESTS:

° SpermCheck Vasectomy for semen
° HemoCue Albumin 201 System for urine albumin
° PSS World Medical Select Diagnostics Strep A Twist for group A Strep

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Board Certification to Qualify as a Laboratory Director

The Commission on Accreditation in Clinical Chemistry is now approved by CMS to provide board certification for laboratory directors.

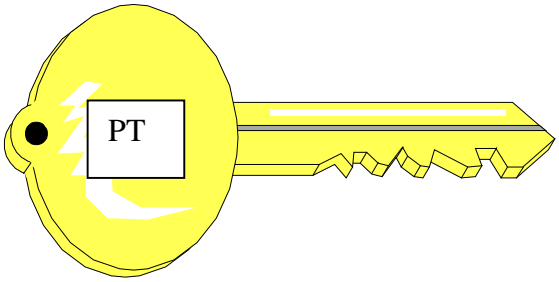
Quality Assessment Spotlight

Every regulatory agency requires some type of quality assurance monitoring to solve laboratory testing problems. Joint Commission requires "root cause analysis" now. About 15 years ago, the laboratory director for Utah Valley Regional Medical

Center (and 4 small rural hospitals), Steven Freestone, MD shared his experience with me on root-cause analysis. At the time, CQI (continuous quality improvement) was the favorite buzzword. He was asked to find out why culture results were taking 48 hrs longer to reach the clinicians in the rural hospitals than in the urban hospital.

Dutifully Dr. Freestone followed CQI principles and convened a multi-departmental team to find and fix the problem. Cultures taken in the rural hospitals were plated and sent by courier to the main hospital lab for incubation and analysis. After some discussion, the team decided if the rural hospitals incubated the cultures first, then sent them to the reference lab they would get faster turn-around time. Dr. Freestone agreed this was a plausible solution, but insisted the team follow the CQI process fully. They mapped out the culture process and decided they should add a computer programmer to the team. After quite some time, the programmer discovered a computer routing problem that delayed results reporting. The problem was solved without the onsite incubation step. Root cause analysis found the "real" solution.

Kudos Dr. Freestone



Proficiency Testing Samples

There is a marked increase in proficiency test referral and communication cases nationally. Debate continues as to whether this represents more cheating or better discovery. The fact remains, the consequences for either action are not worth the appearance of being perfect.

CLIA surveyors require laboratories to have their evaluation results in hand before they use those stored samples for other purposes (competency checks or training samples). Some facilities have many personnel run the samples and turn the results from one run into the provider. Some have been waiting for the reporting deadline to use the samples for QA purposes. But regional office surveyors are warning it may be too difficult to prove you didn't cheat if you have all those results available before you sign the attestation statement that PT samples were treated the same as patient samples. Wait until the evaluation is received and be certain to document when you get the results and when additional testing is done with those samples.

Ponderables:
How is it that we put man on the moon before we figured out it would be a good idea to put wheels on luggage?

SAFETY

Xylene Safety

As you work with chemicals on a daily basis, your ability to detect increased fume exposure diminishes. On the other side, someone new to the area make think they will die from the fumes they smell. Humans can detect 0.08 to 3.7 ppm (parts per million). The National

Institute for Occupational Safety and Health (NIOSH) recommends the maximum exposure limit be 100 ppm. They list the Immediate Danger to Life or Health at 900 ppm.

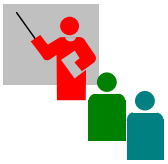
The only way to know your daily exposure does not exceed recommended limits is to have a professional measure an air sample using a NIOSH approved method.

Follow all laboratory safety precautions to prevent over exposure to xylene (or any dangerous chemical).

- Work in a well-ventilated room.
- Work under a certified fume hood.
- Use chemical impervious gloves, boots, aprons and other protective clothing as necessary.
- Use safety glasses, goggles or face shields.
- Do not wear contact lenses when working with xylene.
- Never eat, drink, smoke or apply cosmetics in the laboratory.
- If you need a respirator (when engineering controls are not yet installed or not working, during ventilation repairs, or during an emergency spill), make certain it is Mine Safety and Health Administration as well as NIOSH approved. Anyone using a respirator must have a medical assessment, appropriate training and a fit test.

Live long and work safely.

CONTINUING EDUCATION



NOTE: THE NLTN LENDING LIBRARY CLOSED 7/1/08

DVD

"Verification of Infectious Disease Molecular Assays" is a one hour, intermediate level instructional program from the National Laboratory Training Network (NLTN). For course information and delivery options email customerservice@aphl.org or call 800.536.6586. The course number is 510-401-08 and the cost is $25.

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Laboratory Workshops To Go

Packaging and Shipping Division 6.2 Materials For information, check www.nltn.org/600-08.htm.

Understanding Our Universe

"Astronomers say the universe is finite, which is a comforting thought for those people who can't remember where they leave things."

Anonymous